

4V5330 Carol Lewis
.L4 VISION CORRECTION
2002

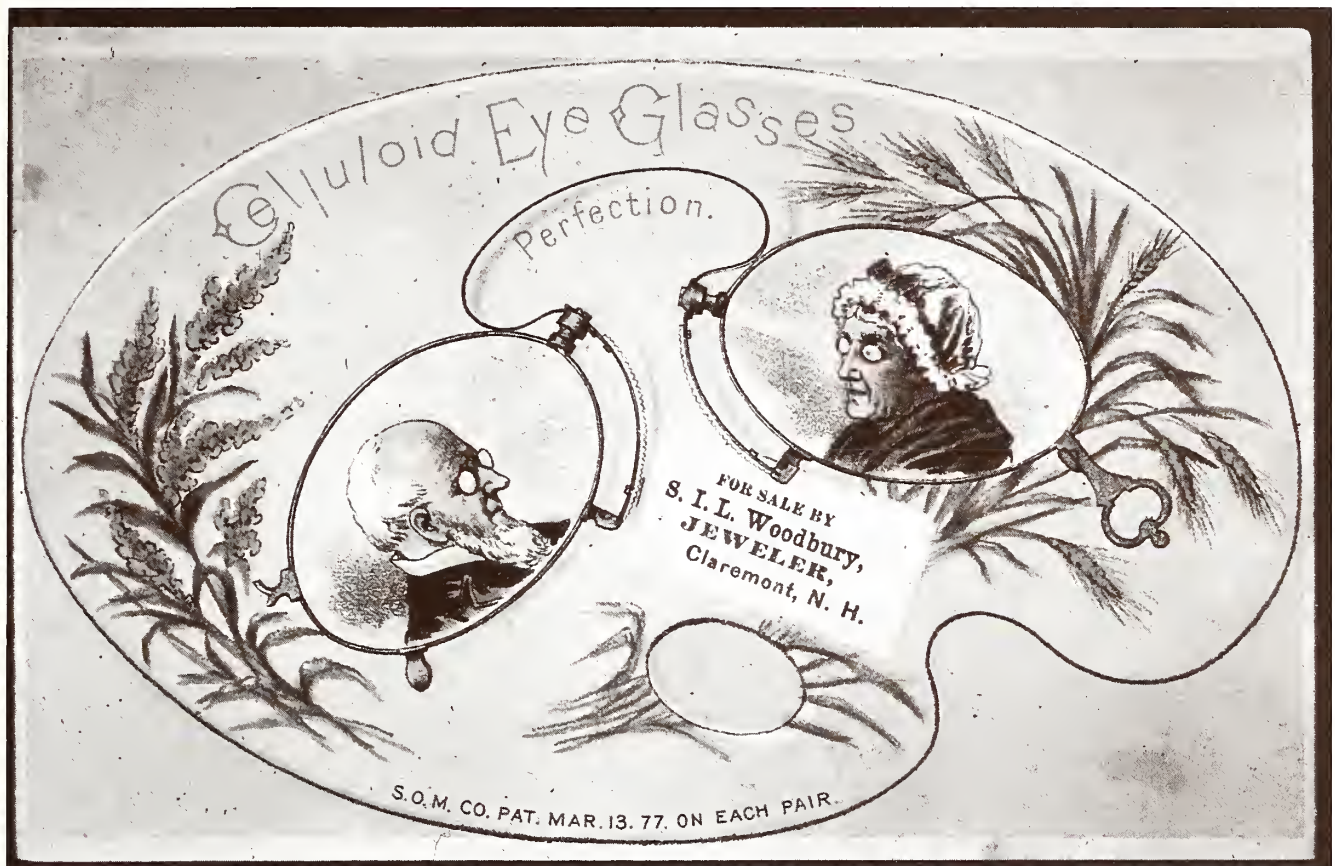
4V5330
.L4
2002

HV5330 Carol Lewis
.L4 VISION CORRECTION
2002

Vision Correction

Taking A Look At What's New

By Carol Lewis



VISION

correction has come a long way since the 13th century when the first pair of spectacles was made by riveting together the handles of two magnifying lenses. Today, surgical developments in vision correction, as well as advances in traditional eyeglasses and contact lenses, can potentially improve a person's vision to better than the optimal range of "20/20."

It's no surprise, then, that people dependent on glasses or contact lenses are visiting their eye-care specialists, hoping to find a quick fix for some age-old vision problems among the array of new techniques, products and technologies. Learning

about some of the common disorders that can threaten vision and how the eye “sees” can help you determine the best treatment to correct your vision. It’s also important to understand the advantages, disadvantages, and limitations that come with vision correction procedures and aids.

How the Eye Sees

Having 20/20 vision means seeing at 20 feet what a person with normal vision sees at 20 feet. A person who has 20/40 vision can see at 20 feet what the person with normal vision sees at 40 feet. And so on.

The eye does not actually “see” objects. Instead, it sees the light that objects reflect. To see clearly, light striking the eye must be bent or “refracted” through the cornea—the clear window at the front of the eye that provides most of the focusing power. Light then travels through the lens, where it is fine-tuned to focus properly on the nerve layer that lines the back of the eye—the retina—and sent to the brain via the optic nerve. The retina acts like the film in a camera, and clear vision is achieved only if light from an object is precisely focused on it. If not, the image you see is blurred. This is called a refractive error.

Refractive errors usually occur in otherwise healthy eyes. They are caused mostly by an imperfectly shaped eyeball, cornea or lens. There are four basic types of errors:

Myopia or nearsightedness—Close objects appear sharp but those in the distance are blurred. The eyeball is longer than normal from front to back, so images focus in front of the retina instead of on it.

Hyperopia or farsightedness—Distant objects can be seen clearly but objects up close are blurred. The eyeball is shorter than normal, so images focus behind the retina.

Astigmatism—Objects are blurred at any distance. The cornea, lens, or both are shaped so that images aren’t focused sharply on the retina.

Presbyopia or aging eye—The eye loses its ability to change focus due to the natural aging process. This usually occurs between ages 40 and 50.

Glasses, contact lenses, and laser eye surgery attempt to reduce refractive errors by making light rays focus properly on the retina.

Laser Eye Surgery—A Popular Alternative

Laser eye surgery is intended for people who want to minimize their de-

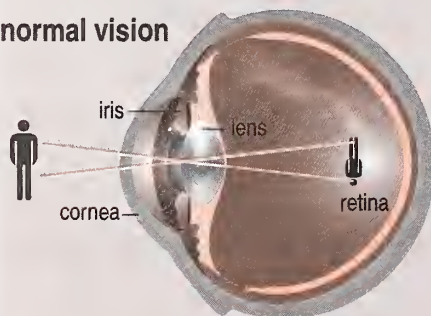
pendency on glasses or contact lenses. Laser surgery can provide vision correction similar to what would be obtained with glasses or contact lenses. People under the impression that surgery can improve their vision beyond what they can see with glasses or contact lenses, however, likely will be disappointed.

By far, the largest increase in laser eye surgery interest recently has been in a procedure called “laser *in situ* keratomileusis,” popularly known as LASIK. Advertising for this technique appears prominently on broadcast outlets, including the Internet and in newspapers and magazines. Fortunately, says Terrence P. O’Brien, M.D., a spokesman for the American Academy of Ophthalmology (AAO), most surgeons and medical centers are doing a good job of educating the public about the risks and benefits of LASIK. “But patients need to be very well-informed in advance,” he says.

LASIK permanently changes the shape of the cornea, and is performed for varying degrees of nearsightedness, farsightedness, and astigmatism. A surgical knife, called a microkeratome, is used to cut a flap in the cornea, leaving a hinge at one end of the flap. The flap is then folded back to reveal the middle

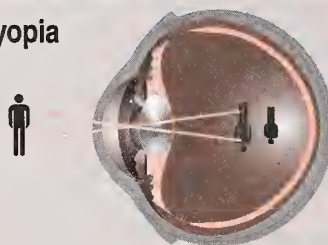
How We See It

normal vision



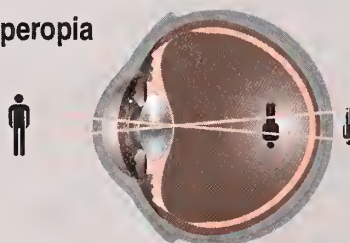
The cornea and the lens are responsible for focusing light on the retina. With normal vision, light striking the cornea is focused directly on the central region of the retina.

myopia



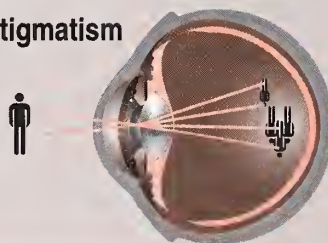
Myopia, or nearsightedness, occurs when either the cornea is too steep and/or the eye is too long, and light is focused in front of the retina. Close objects appear clear and far objects are blurry.

hyperopia



Hyperopia, or farsightedness, occurs when either the cornea is too flat and/or the eye is too short, and light is focused behind the retina. Distant objects appear clear and close objects appear blurry.

astigmatism



Astigmatism occurs when the surface of the cornea is oval-shaped, rather than round. Light rays have more than one focal point and can focus on different areas of the retina. Astigmatism creates double, distorted or blurry vision.

layer of the cornea, called the stroma. Pulses from a computer-controlled excimer laser vaporize a portion of the stroma and the flap is then replaced. By removing this tissue, the shape of the central cornea is changed, and the refractive error is reduced.

O'Brien, who is also director of refractive surgery at the Wilmer Eye Institute at Johns Hopkins University in Baltimore, has performed over 10,000 eye surgeries. Still, he warns that people considering LASIK need to be wary of ads that make excessive promises.

"Price should not be the first factor" in considering to have delicate eye surgery, he says. "People fear blindness second only to cancer, and just as they wouldn't consider a discount open heart operation or budget brain surgery, they shouldn't take a chance with their eyes." The real struggle, he says, is in training doctors. "The most advanced technology and precise laser will give poor results if you don't have an experienced, capable surgeon."

This latest hype about LASIK's now-more-affordable advantage, coupled with some pretty appealing results, makes surgery one of the most exciting vision correction options available. Doctors say that LASIK gives a rapid visual recovery, with minimal pain, and little or no post-operative discomfort. In fact, most people who undergo LASIK, like Beth Polazzo—one of O'Brien's patients—can see well enough to drive immediately after surgery, and usually have excellent vision within a week.

"I had good vision immediately," says the 54-year-old Brooklyn, N.Y., resident, even though eventually one eye had to be retreated. "This is the best I've seen since I was seven years old." The laser does its work on each eye in less than a minute, and patients are typically back to work or normal activities within three days.

While most people are pleased with the results of their surgery, O'Brien says that, as with any medical procedure, there are risks involved. Some include: over- or under-treatment; the inability to wear contact lenses; permanent loss of vision; reduction in the quality of vision including the development of glare, halos, and starbursts; difficulty with night-driving; and reduced vision in dim light-



ing conditions. The risks are doubled when both eyes are treated at the same time.

Also, LASIK is not reversible. That's why in Polazzo's case, O'Brien intentionally undercorrected her distance eye. "We were aiming for modified monovision," he explains, which means that one eye would see close up while the other would be corrected to see distances. But Polazzo experienced some regression in her distance eye—that is, her distance vision began to worsen as she returned to nearsightedness—some weeks following surgery. However, because of the initial undercorrection, O'Brien was able to fix the problem.

A. Ralph Rosenthal, M.D., director of the Food and Drug Administration's division of ophthalmic and ear, nose and throat devices in the Center for Devices and Radiological Health, says that no one knows the long-term effects of laser eye surgery. "We just can't know that yet," he says, so when people call looking for a guarantee in years for the success of the procedure, "I can't give them one."

Before undergoing LASIK, Rosenthal says people should carefully weigh the risks and benefits based on what's important to them, and potential side effects, including the pros and cons of having one or both eyes done on the same day. It's also important to avoid

being influenced by friends who have had LASIK surgery or doctors who encourage patients to do so.

For more on LASIK, such as what to expect before, during and after surgery, and how to find the right doctor, visit the FDA's special LASIK Web site at www.fda.gov/cdrh/lasik/.

A second laser procedure used today as an alternative to LASIK is photorefractive keratectomy, or PRK. Although O'Brien says that less than 5 percent of people undergo PRK, it is still the procedure of choice for certain eye conditions. This type of refractive surgery gently reshapes the cornea by removing microscopic amounts of tissue from the outer surface with a cool, computer-controlled ultraviolet beam of light. It does not, however, involve cutting. The procedure takes only a few minutes, and patients are typically back to daily routines in five to seven days.

Clinical studies indicate that about 5 percent of PRK recipients continued to need glasses for distance vision following the surgery, and up to 15 percent need glasses occasionally, such as when driving. In addition, many people experienced mild corneal haze following surgery, which is part of the normal healing process. The haze appeared to have little or no effect on final vision, and could only be seen by a doctor under a microscope. For about 5 percent of PRK patients, best-corrected vision without cor-

Eye Tips

While you can't do anything about age or genetic makeup, you can eat a balanced diet, wear sunglasses that block ultraviolet light, and get regular eye exams to help maintain good vision. Regular eye exams are important because they can detect early signs of disease long before the disease leads to vision loss. Doctors recommend that everyone have an eye exam shortly after birth, and at least every few years until age 40. After that, the eyes should be routinely checked every 2 or 3 years. ■
—C.L.

rective lenses was slightly worse after surgery than before. These conditions, however, improved or disappeared in most people in six months.

Another new, less-invasive laser procedure—indicated for temporarily reducing hyperopia—is being aimed exclusively at people over 40. Laser thermal keratoplasty, or LTK, involves zapping 16 spots on the outer part of the cornea to shrink the tissue. People usually can leave 30 minutes after the procedure and resume normal activities the following day. The advantage of LTK is that it's a "no touch" procedure, meaning there's little chance of infection or loss of vision. The disadvantage is that the procedure is considered temporary since the treatment effect regresses—for many people, about half of the correction is gone within two years. Another drawback is that people may become nearsighted in the first six weeks, enough to require glasses for driving, and their vision can fluctuate for weeks after surgery.

Rosenthal wants people considering laser surgery to know and carefully weigh the pros and cons. "FDA mandated that manufacturers of all excimer lasers make available to people a patient information booklet," he says, that spells out this information. If the doctor fails to offer one, Rosenthal says that you should ask for it.

Experts say that the reliability of laser vision correction is quite good in mild to moderate levels of refractive errors. But people desperate for clear vision need to understand the dangers. The most satisfied laser surgery patient is one who has realistic expectations and a thorough understanding of the risks and possible complications of refractive surgery.

Contact Lenses—More Choices

Whether you're interested in wearing contact lenses for the first time, or are considering an upgrade for comfort and convenience, discussing the latest innovations with your eye-care practitioner will help make your choices easier and minimize the risks. Advances in materials for precision lenses have made soft and rigid gas permeable contacts—the two main contact lens groups—an option for more people. These medical devices are made of many different types



For More Information

FDA

Division of Small Manufacturers,
International, and Consumer
Assistance
Consumer Assistance Staff (HFZ-210)
1350 Piccard Drive
Rockville, MD 20850
1-888-INFO-FDA (1-888-463-6332)
(follow touch-tone prompts to get
information about medical devices)
www.fda.gov/cdrh/consumer/index.shtml

National Eye Institute
National Institutes of Health
31 Center Drive, MSC 2510
Bethesda, MD 20892-2510
301-496-5248
www.nei.nih.gov

American Academy of Ophthalmology
P.O. Box 7424
San Francisco, CA 94120-7424
www.aao.org

American Optometric Association
243 N. Lindbergh Boulevard
St. Louis, MO 63141
www.aoanet.org

of plastic, and offer numerous options. With daily wear or extended wear (overnight) lenses, the options include frequent- or planned-replacements, disposables, bifocals, UV-blocking contacts, and more. There are clear, tinted, opaque, spherical and rounded lenses. So where does someone start when deciding if contact lenses are the right choice for vision correction, and what to choose?

Hal Balyeat, M.D., professor of ophthalmology at the University of Oklahoma's Dean A. McGee Eye Insti-

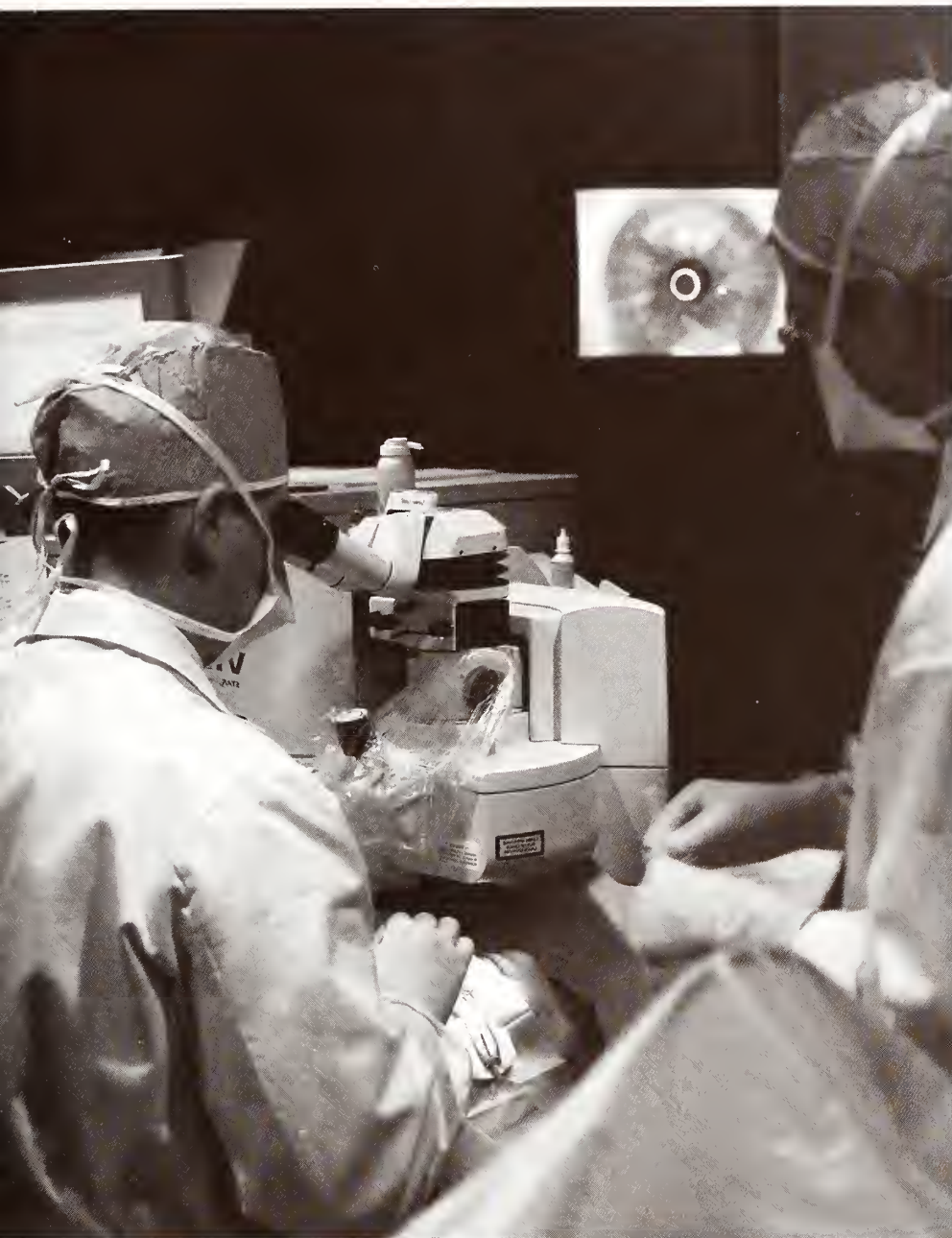
tute, says people satisfied with their vision correction may not need to look very far. "If you are already a satisfied contact wearer," he says, "you may not consider other options worthwhile when you're wearing your contacts as well as you are." Satisfied wearers typically have no allergies and have not developed an intolerance to contact lenses. The bottom line: If contact lenses are working for you, Balyeat says, it's hard to justify other options, such as permanent laser alteration of otherwise healthy eyes.

Balyeat cites his wife, Marilyn, as an example. Although she was a good candidate for the LASIK surgery, she opted for monovision contacts—one lens focuses close up while the other lens corrects for distance vision. "At 60," she says, "I can still read without glasses." And that, says her husband, is the single most important factor: "If you like being able to take out your contacts and still see up close, surgery is not a worthwhile trade-off." Balyeat adds that many people don't realize that laser surgery, performed on people over 40, won't let you see up close without glasses or contacts unless you opt for monovision LASIK.

Contact lens quality continues to improve. Soft contacts contain from 25 percent to 79 percent water, are easy to adjust to, and are more comfortable than rigid gas permeable (RGP) lenses, thanks to their ability to conform to the eye and absorb water. Soft lenses aren't likely to pop out or capture foreign material such as dust underneath, as hard lenses are. Extra-thin soft lenses are available for very sensitive eyes.

While the ability to hold water increases oxygen permeability of soft lenses, it also makes them more fragile. And soft lenses are more likely to absorb chemicals and residues on the wearer's hands.

RGP lenses are more durable and resistant to deposit buildup, and they generally give clearer, crisper vision. They tend to be less expensive over the life of the lens, but the initial cost often is higher. RGP contacts last several years, while soft contacts, depending on the type, are meant to be replaced after periods ranging from a day to about a year. In addition, RGP lenses can be marked



Constance Dicembre waits for the countdown that prompts the laser application. A lid speculum is placed between her eyelids to prevent her from blinking.

Terrence O'Brien, M.D., (left) performs LASIK eye surgery at Johns Hopkins University's Wilmer Eye Institute in Baltimore. O'Brien first surgically creates a flap of corneal tissue less than the thickness of a human hair and lifts it to one side. Assisted by associate Marc Winnick, M.D., O'Brien then applies laser energy to reshape the cornea according to carefully calculated measurements. The monitor on the wall shows the precise location of the laser beam on the cornea. Finally, the flap, which serves as a naturally adhering bandage, is repositioned.

to show which lens is for which eye, and they're less likely to tear or rip, making them easier to handle. However, it often takes several weeks to get used to wearing rigid lenses, compared with several days for soft.

Many changes are occurring in the world of disposable (defined by the FDA as used once and discarded) and frequent- or planned-replacement contacts. The latest innovations include daily disposables, bifocals and toric contacts for astigmatism.

"It's healthier to replace lenses more often," says James Saviola, O.D., chief of the vitreoretinal and extraocular de-

vices branch in the FDA. "And if you reuse your lenses, you need to do something more than store them in saline solution." The FDA approved in 2000 the first "no-rub" cleaning solution for contact lenses. The solution adds a safeguard for people who do not rub their lenses—but should—when cleaning. The no-rub directions for this first solution initially applied to lenses replaced within a month or less. Now, it has been expanded to include lenses that are replaced after a month or more. Other products also are available that have no-rub directions for lenses replaced within a month. But Saviola reminds people

that in some cases, rubbing is still necessary to keep their lenses clean.

A new generation of lens materials is being studied. Lenses made of these materials provide a greater amount of oxygen permeability, says Saviola. Two types already have received FDA approval, one for seven days of continuous wear, the other for 30 days.

The most serious safety concerns with any contact lens deal with overnight use, or extended-wear. Rigid or soft, wearing these types of contacts overnight increases the risk of corneal ulcers—infection-caused eruptions on the cornea that can lead to blindness. Symptoms in-

clude vision changes, eye redness, eye discomfort, and excessive tearing. Extended-wear rigid lenses also can cause unexpected, sometimes undesirable reshaping of the cornea. Saviola advises that keeping lenses clean, replacing them often, and wearing them as prescribed by your eye-care specialist increases the safety of wearing contacts.

People should not wear contact lenses longer than the time prescribed by their eye-care practitioner. But whatever he or she prescribes, be sure to ask for written instructions and follow them carefully. Patient package inserts usually accompany contact lenses, and Saviola emphasizes that people who are not offered this information by their doctors should ask for it.

For those who haven't been able to wear contacts, implantable lenses may be an option in the future.

Orthokeratology

Orthokeratology, or Ortho-K, is a procedure that uses RGP contact lenses to change the curvature of the cornea to improve its ability to refract light and successfully focus on objects. Unlike regular RGPs, Ortho-K RGPs have a design that can reshape the curvature of the cornea. This method, however, does not produce a permanent result.

With conventional Ortho-K, the lenses are worn about eight hours a day. After the cornea has achieved the best shape for optimal vision, the lenses are worn less frequently—perhaps for a few hours every two or three days. If someone starts and then discontinues Ortho-K, says Saviola, the corneas will eventually return to their natural state. People choose Ortho-K over refractive surgery because Ortho-K's effects are not permanent.

One disadvantage of Ortho-K is that clear vision may fluctuate during the day. Also, Ortho-K may take many months to change a person's vision. A more advanced technique known as "accelerated Ortho-K" takes less time, and may be recommended to achieve a rapid effect.

Since 1998, Saviola says the FDA has cleared a number of daily wear Ortho-K lenses, but overnight Ortho-K lenses have not been approved.

The best candidates for prescription Ortho-K are people of any age who have

low amounts of nearsightedness or astigmatism. The goal is to bring the person's vision to at least 20/40. But for some, Ortho-K will provide 20/20 vision.

Corneal Ring Segments

In 1999, the FDA approved a non-laser surgical procedure for correcting small amounts of nearsightedness. Corneal ring segments are tiny, clear crescent-shaped pieces of plastic polymer that are implanted in the cornea. The ring segments reshape the cornea so that it becomes flatter, allowing it to focus light rays onto the retina and producing sharp vision. The procedure takes about 15 minutes and is done on an outpatient basis. Before surgery, anesthetizing drops are placed in the eyes.

Corneal rings are still being studied to treat mild hyperopia and astigmatism, although these uses have not been approved by the FDA. Several other intraocular and corneal implants, from several companies, also are in various stages of clinical study.

Eyeglasses—The Old Standby

In some cases, modern technology can provide the best vision correction option. In those cases in which it can't, eyeglasses can often help. Glasses correct refractive errors by adding or subtracting focusing power to the cornea and lens. The power needed to focus images directly on the retina is measured in diopters. This measurement is also your eyeglass prescription.

Like contact lenses, glasses come in all shapes and sizes, offering an array of choices for both function and fashion. Eyeglass frames, for example, are more durable and tout materials such as titanium and new "memory metals." Lenses are thinner, stronger and lighter. Lens options include antireflective coating, light-changing tints, progressive (line-free) bifocal lenses, and polycarbonate—the most impact-resistant lens material available.

Perhaps the greatest troubling aspect for eyeglass wearers is the constant feel of something sitting on the nose, despite such advances as featherweight glasses. Paul Trossevin of Falling Waters, W.Va., knows all too well the uncomfortable feeling of something permanently



perched on his nose. Like a scar that never fades, Trossevin's glasses have been with him every day since he was 4 years old. Now 35, he says, "There was a time when I'd have done anything to get rid of my glasses." Or so he thought.

Although he could never wear contact lenses because of the severe flatness of his cornea, Trossevin was a candidate for laser eye surgery. But the one thing he was unable to obtain from any doctor was a guarantee that after surgery he wouldn't see starbursts and halos around lights—a big concern since he drives a good part of the day and plays baseball at night. "The guarantee was everything," he says. "When he couldn't give me that, suddenly my glasses took on new meaning—a guarantee of the good eyesight they have given me for over 30 years."

Looking Ahead

Among some of the more intriguing developments in the vision-correction pipeline is an alternative to LASIK, called LASEK, a new avenue for refractive surgeons that disturbs less corneal tissue than its sound-alike counterpart. There's also talk of investigational devices that could be placed inside the eye to correct refractive errors. Over the next decade, there are sure to be improvements in current techniques and technologies, in addition to new procedures. ■

Carol Lewis is a staff writer for FDA Consumer.

Buying Contact Lenses by Phone, Mail or the Internet

If you buy contact lenses—an FDA-regulated product—on the Internet, over the phone, or by mail, the agency wants you to be well-informed. While such purchases are often a convenient and economical way to get your lenses, consumers need to exercise caution when using alternatives to a prescription from an eye-care specialist, or reputable pharmacy. The following information and tips can help:

Health-Related Information

- Get regular eye exams. You may have problems with your eyes that you are not aware of, and your contacts may not correct your vision properly. Some untreated infections can lead to blindness.
- Have an eye-care specialist check to make sure that your contact lenses fit properly and that the contact lens prescription was filled properly. Failure to do so could cause discomfort or damage to your eyes.
- Beware of attempts to substitute a different brand than what you normally wear. There are differences in water content and shape between brands. The choice of which lens is right for you should be made only based on examination by your eye-care specialist, not over the phone or the Internet.
- Request the manufacturer's written patient information for your contact lenses. It will give you important information, as well as instructions for use.

Prescription-Related Information

- The minimum elements contained on a valid contact lens prescription should include your name, doctor's name, contact lens brand name and material, expiration date (if mandated by your state), and lens measurements, including power, diameter and base curve.
- Make certain your contact lens prescription is current when ordering. The

expiration date is currently set by each state. Some states require one- or two-year expiration dates, while other states leave it to eye care-specialists to decide. Never order lenses using a prescription that has expired.

- Be sure the lenses the company sends matches your prescription exactly. Check that you have the brand and lens name you ordered, and that the numbers indicating power, sphere, cylinder and axis (if any), diameter, and base curve are the same as on your prescription. This information is required to appear on the contact lens package or container.
- If you think you have received an incorrect lens, check with your doctor. Don't accept substitutes for any contact lens unless your doctor approves.
- Some Internet sites ask for information about your doctor so that they can check the prescription. If they do check and receive a verbal OK, then they have complied with the Federal prescription device regulation. If the company does not check, they have not obtained a valid prescription. Some state laws require that a written prescription be presented.
- Order your contacts from a supplier you are familiar with and know is reliable.
- You won't break any laws if you buy lenses on the Internet, by phone, or through the mail without a prescription, but you should know that the company



is selling you a prescription device as if it were an over-the-counter device. This violates federal regulation. Be wary when companies tell you they will check with your doctor to confirm the prescription. They don't always check.

Problems Relating to Purchases

- Report serious eye problems associated with your lenses to the FDA's MedWatch reporting program at www.fda.gov/medwatch/. Also, contact your health professional for medical advice.
- Report problems involving contact lens sales by Web sites by sending an e-mail to webcomplaints@ora.fda.gov.
- If you do not get the exact lenses you ordered, you should report the problem directly to the company that supplied them. ■

—C.L.

Charge your order. It's easy.



For privacy protection, check the box below:

☐ Do not make my name available to other mailers

Check method of payment:

☐ Check payable to Superintendent of Documents☐ GPO Deposit Account☐ VISA ☐ MasterCard ☐ Discover/NOVUS[illegible]

				(expiration date)
--	--	--	--	-------------------

Mail to:

Superintendent of Documents

PO Box 371954

Pittsburgh, PA 15250-

Authorizing signature

Important: Please include this completed order form with your remittance.
Subscribe to *FDA Consumer* online at www.fda.gov/fdac/orderform/fdap.html

Thank you for your order!

FDA Consumer

DEPARTMENT OF HEALTH AND HUMAN SERVICES • Food and Drug Administration

FDA on the Internet: www.fda.gov

We hope you found this reprint from *FDA Consumer* useful and informative. *FDA Consumer*, the magazine of the U.S. Food and Drug Administration, provides a wealth of information on FDA-related health issues: food safety, nutrition, drugs, medical devices, cosmetics, radiation protection, vaccines, blood products, and veterinary medicine. For a sample copy of *FDA Consumer* and a subscription order form, write to: Food and Drug Administration, HFI-40, Rockville, MD 20857.

The contents of this publication—both text and graphics—are not copyrighted. They are in the public domain and may be republished, reprinted, and otherwise used freely by anyone, without the need to obtain permission from FDA. Credit to the U.S. Food and Drug Administration as the source is appreciated but not required. We also appreciate being informed about the use of our materials. Contact FDA, HFI-40, Rockville MD 20857, or e-mail FDAC-letters@oc.fda.gov.

PUBLICATION NO. (FDA) 02-4266

